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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/035,783 | 12/24/2001 | Michael Graupe | 1016US | 3968 |

7590

06/11/2003

Celera, An Applera Corporation Business
180 Kimball Way
South San Francisco, CA 94080

EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 06/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/035,783 | GRAUPE ET AL. | |
| | Examiner | Art Unit | |
| | Robert Shiao | 1626 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Application received on 12/24, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,13-15 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 30 is/are rejected.
- 7) ☒ Claim(s) 1-7,11,12,16-24,28,29 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the provisional application: 60, 257,603 with a filing date 12/22/2000.
2. Claims 1-31 are pending in the application.

Responses to Applicant's Election/Restriction

3. Applicant's election with traverse of Group II claims 1-7, 10-12, 16-24, and 28-31 in Paper No. 0503, dated May 9, 2003, is acknowledged. A compound 2-(2, difluoromethoxy-benzylsulfonylmethyl)-N-[1-(5-ethyl[1,3,4]oxadiazole-2-carbonyl)butyl]-4-morpholin-4-yl-4-oxo butyramide has been elected as the single disclosed species. The traversal is on the grounds that division into separate groups by restriction requirement of the instant invention is improper. A number of case laws including *Ex parte Holt*, USPQ 381, *In re Haas I*, 179 USPQ 623, *In Re Haas II*, 198 USPQ 334, and *In re Weber*, 198 USPQ 331 were cited by applicants. This is not found persuasive and reasons are given as follows.

In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more

members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Group of the restriction requirement is directed to or involves compounds and their processes of making which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over the other invention (Group), i.e. they are patentable over each other. Chemical structures which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebuttable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The groups of the restriction requirement represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

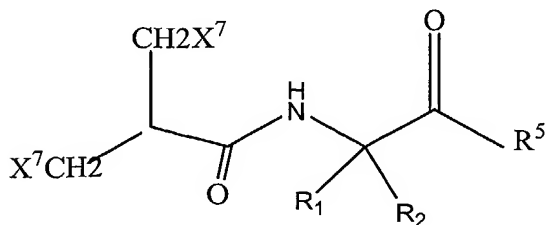
Inventions of Group I-IV are independent and distinct processes because compounds/composition and their process for making and Methods of use of each group differ in elements, bonding arrangement and chemical property to such an extent that a reference anticipating compounds of any one group would not render another group obvious. The search for compounds of Group I is not required for another group (i.e., Group II) and is not coextensive of each other. In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

4. Claims 1-31 are pending in the application. The generic concept of the elected subject matter is as follows:

A compound of formula I(b) of claim 10,



wherein

the X^7 of X^7CH_2 is $-X^4C(O)R^{15}$, and X^4 is a bond, R^{15} is hetero(C_{3-10})cycloalkyl(C_{0-3})alkyl, i.e., R^{15} is morpholine;

the X^7 of $\begin{array}{c} CH_2X^7 \\ | \end{array}$ is $-X^4S(O)_2R^{15}$, and X^4 is a bond, R^{15} is (C_{6-10})aryl(C_{0-6})alkyl optionally substituted with halo-substituted $C_{(1-4)}$ alkyl, $-X^4OR^{13}$, $-X^4C(O)R^{13}$, or $-X^4OC(O)R^{13}$, and X^4 and R^{13} are as defined in claim 1, i.e., R^{15} is benzyl;

R^1 is hydrogen, or (C_{1-6})alkyl;

R^2 is as defined in claim 1 except hetero(C_{3-10})cycloalkyl(C_{0-3})alkyl;

R^5 is as defined in claim 11.

The above generic concept compound of formula I is classified in class 544/111+.

As a result of the election and corresponding generic concept identified, claims 1-7, 10-12, 16-24, and 28-31 embraced by above generic concept, are prosecuted in the case, claims 8-9, 13-15, and 25-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention. The withdrawn subject matter of claims 8-9, 13-15, and 25-27 is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from, i.e., the fields of search are not co-extensive.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

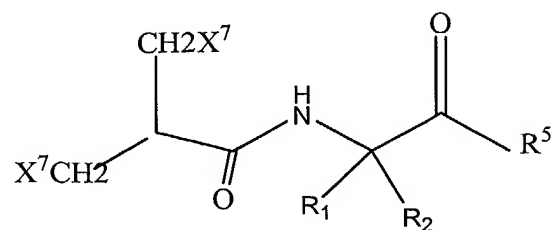
Claim 30 provides for the use of treating a disease in an animal in which Cathepsin S activity contributes to the pathology, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 30 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Double Patenting

6. Claim 10 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending application No.10183128. Although the conflicting claims are not identical, they are not patentably distinct from each other because:
Applicants claim a compound of formula I(b),

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wherein

the X^7 of X^7CH_2 is $-X^4C(O)R^{15}$, and X^4 is a bond, R^{15} is hetero(C_{3-10})cycloalkyl(C_{0-3})alkyl, i.e., R^{15} is morpholine;

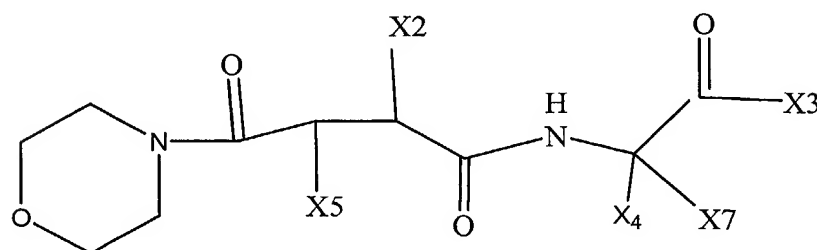
the X^7 of CH_2X^7 is $-X^4S(O)_2R^{15}$, and X^4 is a bond, R^{15} is (C_{6-10})aryl(C_{0-6})alkyl optionally substituted with halo-substituted $C_{(1-4)}$ alkyl, $-X^4OR^{13}$, $-X^4C(O)R^{13}$, or $-X^4OC(O)R^{13}$, and X^4 and R^{13} are as defined in claim 1, i.e., R^{15} is benzyl;

R^1 is hydrogen, or (C_{1-6})alkyl;

R^2 is as defined in claim 1 except hetero(C_{3-10})cycloalkyl(C_{0-3})alkyl;

R^5 is as defined in claim 11.

Graupe et al. '128 claim a compound of formula I,



wherein X^2 is sulfonyl alkyl motif; X^3 is heterocycle; X^5 is hydrogen, or $-O-R$, and R is a straight or branch alkyl containing 1-6 carbon atoms;

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X⁴ and X⁷ are independently hydrogen or –R, and R is a straight or branch alkyl containing 1-6 carbon atoms. A compound N-[(S)-1-(5-ethyl-1,2,4-oxadiazole-3-carbonyl)-propyl-4-morpholin-4-yl-4-oxo-2-phenylmethanesulfonylmethyl-butylamide has been specifically exemplified in the specification.

The difference between Graupe et al. '128 and the instant claim is that variable X⁵ of formula I of Graupe et al. can be hydrogen or alkyl, while it is hydrogen in the instant compound.

One having ordinary skill in the art would find the instant claim *prima facie* obvious **because** one would employ the compound of Graupe et al., wherein X² is sulfonyl alkyl motif, X³ is heterocyclic motif (i.e., oxadiazole), X⁵ is hydrogen, X⁴ and X⁷ are independently hydrogen or a straight or branch alkyl containing 1-6 carbon atoms (i.e., butyl), which is the instantly claimed compound. The motivation to prepare the instantly claimed compounds drives from the expectation that structurally similar compounds are expected to possess similar properties and methods of use.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Objection

8. Claims 11-12 are objected to as being dependent upon a rejected base claim and containing non-elected invention, but would be allowable if delete non-elected invention and rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1-7, 16-24, 28-29, and 31 are objected to as containing non-elected invention, but would be allowable if delete non-elected invention and rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Telephone Inquiry

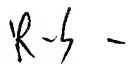
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (703) 308-4002. The examiner can normally be reached on 8:30 AM - 5:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K McKane can be reached on (703) 308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


Robert Shiao, Ph.D.
Patent Examiner
Art Unit 1626

June 3, 2003


Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626